510(k) Summary

APR - 9 1998

K965034

Submitter:

Edgar Cohen
Hemostace, L.L.C.
4123 Vinncennes Place
New Orleans, Louisiana 70125

Date Summary was Prepared:

April 8, 1998

Name(s) of the device:

Sorbastace

Identification of predicate device(s):

Iodosorb Powder, Intrasite Cavity Wound Dressing, Kaltostat Wound Dressing, ClearSite Hydrogel Wound Dressing, and DeRoyal Hydrogel Dressing.

Description of the device:

The device consists of fine granules of a biocompatible polymer which encapsulate micron-sized particles of an astringent product. The granular product is packaged in single-patient use packets for convenient sprinkling into fresh traumatic, superficial lacerations or wounds.

The device in intended to be applied to fresh, traumatic, superficial lacerations or wounds to absorb body fluid and stop minor bleeding. Once exudation and bleeding has stopped, it is irrigated from the wound and a protective dressing can be applied.

The polymeric granules absorb fluid into their interior spaces and adsorb fluid onto their surfaces, in volume approximately equal to the volume of the granules. The relatively large surface area of the granules fosters coagulation. Within the interior space of the granules, the astringent is dissolved by the fluid. The astringent released from the granules then acts within the wound site to have a local and limited protein coagulant effect to help arrest secretion and stop minor bleeding.

Intended Use:

Sorbastace in indicated for use to absorb body fluid and to stop minor bleeding in fresh traumatic superficial lacerations or wounds. Once exudation and bleeding has stopped, it is irrigated from the wound and a protective dressing can be applied. It is intended to be distributed as an Over-The-Counter (OTC) device.

Comparison of device characteristics to predicate:

Sorbastace consists of fine granules of a biocompatible polymer which encapsulate micron-sized particles of an astringent product. These characteristics compare to the cross-linked cadexomer beads with iodine of the Iodosorb Powder, the calcium-sodium alginate fiber of Kaltostat Wound Dressing, and the polyurethane foam chips and polymeric cover of Intrasite Cavity Wound Dressing.

Non-clinical testing:

Sorbastace has been evaluated for biocompatibility by subjecting it to the following battery of *in vitro* and animal tests: cytotoxicity, dermal sensitization, dermal irritation, acute system toxicity, and hemolysis. The retention and deposition of Sorbastace was evaluated through histopathological examination of animals treated with the device. Also, the absorbed dose of the astringent was measured and compared to that of absorption of aluminum sulfate of OTC styptic pencils subject to an FDA monograph. The capacity to absorb fluid was measured in an *in vitro* test. Tests in animals were performed to evaluate the ability of Sorbastace to stop minor bleeding in comparison to predicate device intended for the same use. Bacteriostatic and bactericidal activity of Sorbastace was evaluated for some common wound pathogens.

Clinical testing:

Clinical studies were not performed.

Conclusion:

Sorbastace has intended use in common with predicate devices. Sorbastace has technological characteristics common to these predicate devices. With regard to safety, Sorbastace is biocompatible as are the predicate devices and would present less absorbed dose of aluminum sulfate than the OTC styptic pencils subject to an FDA monograph. Therefore, Sorbastace is substantially equivalent to predicate, preamendment devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Hemostace, L.L.C.
c/o David L. West, Ph.D.
Senior Technical Advisor
MTC Quintiles
15825 Shady Grove Road, Suite 90
Rockville, Maryland 20850

Re: K965034/S2
Trade Name: Sorbastace
Regulatory Class: Unclassified
Product Code: FRO
Dated: January 9, 1998
Received: January 9, 1998

Dear Dr. West:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act). You may, therefore, market your device subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act) and the following limitations:

1. This device may not be labeled for use on third degree burns.

2. This device may not be labeled as having any accelerating effect on the rate of wound healing or epithelization.

3. This device may not be labeled as a long-term, permanent, or no-change dressing, or as an artificial (synthetic) skin.

4. This device may not be labeled as a treatment or a cure for any type of wound.

The labeling claims listed above would be considered a major modification in the intended use of the device and would require a premarket notification submission (21 CFR 807.81).

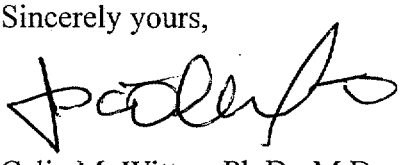
The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practices, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations (CFR), Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practices (GMP) for Medical Devices: General GMP regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or 301-443-6597 or at its internet address http://www.fda.gov/cdrh/dsmamain.html.

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

510(k) Number K965034

None assigned at this time.

Device Name

Sorbastace

Indications for Use

Sorbastace is indicated for use to absorb body fluid and to stop minor bleeding in fresh traumatic superficial lacerations or wounds. Once exudation and bleeding has stopped, it is irrigated from the wound and a protective dressing can be applied. It is intended to be distributed as an Over-The-Counter (OTC) device.

Concurrence of CDRH, Office of Device Evaluation (ODE)

☐ **Prescription Use (per 21 CFR 801.109)**

☒ **Over-The-Counter Use**

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K965034